

SEP 27 2001

K012078

### 510(K) SUMMARY

Manufacturer:	Fixano S.A. Z.A. Les Bruyeres 01960 Peronnas France
Submitted By:	Ferguson Medical Consultant to Fixano S.A.
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories.
Common/Usual Name:	External fixation device, wrist fixator, and others.
Proprietary Name:	Radiofix
Classification Number:	21 CFR 888.3030/Procode 87 KTT
Substantial Equivalence:	Orthofix Non-bridging Pennig Wrist Fixator, orthopedic Innovations Cobra External Fixator (K983881), and others.
Device Description:	The device is a radiolucent external fixator capable of rotation and angulation.
Intended Use:	The intended use is similar to that for other external fixators.
Technological Characteristics:	The Radiofix device is similar in its intended use to predicate devices and existent methodologies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 27 2001

Mr. Frank Ferguson  
C/o Fixano S.A.  
Ferguson Medical  
P.O. Box 12038  
La Jolla, California 92039-2038

Re: K012078

Trade/Device Name: Radiofix  
Regulation Number: 888.3030  
Regulation Name: Single/Multiple Component Metallic Bone  
Fixation Appliances and Accessories  
Regulatory Class: II  
Product Code: KTT  
Dated: May 25, 2001  
Received: July 2, 2001

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

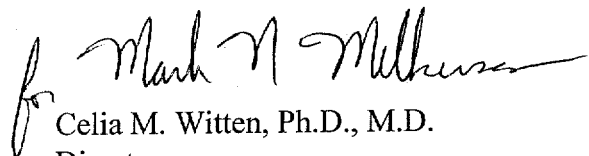
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Frank Ferguson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (If known): K012078

Device Name: Radiofix

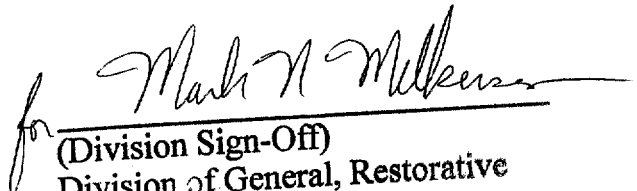
Indications For Use:

The Fixano Radiofix wrist fixation device is intended for use in the fixation of unstable or comminuted extra-articular epiphyseal fracture of the distal radius, by compression, flexion or extension. The epiphyseal fragment must be in one single piece.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices  
510(k) Number K012078

Prescription Use XX  
(Per 21 CFR 801.109)

OR

Over-The- Counter Use \_\_\_\_\_